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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,310	08/25/2000	Paul B. Fisher	62943/JPW/JML	6406
7590	03/23/2004		EXAMINER	
Lisa B. Kole Baker Botts L.L.P. 30 Rockefeller Plaza New York, NY 10112			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,310

Applicant(s)

FISHER ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

All the rejections of record are moot because applicant canceled all previously examined claims and presented new claims 54-85.

Claims 54-85 are pending and are under consideration.

This rejection contains new grounds of rejection.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The Following are New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 54-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has two parts: written description, and new matter rejections.

First, the base claims 54 and 70 as construed read on an isolated nucleic acid comprising SEQ ID NO:2 or 4 protein coding region plus an native enhancer region controlling the transcription of said coding region because the specification at the paragraph bridging pages 12 and 13 defines "enhance element" as "a nucleotide sequence that increases the rate of transcription of the therapeutic genes or genes of interest". In other words, the specification as originally filed does not limit "an enhancer" to an art-known enhancer only. Both SEQ ID NO:2 and SEQ IDD NO:4 encoding

nucleic acid molecules are from mammalian species with an native enhancer present in order to control transcription as reviewed by Voet et al (Biochemistry, John Wiley & Sons, 1990, page 866 only). This definition indicates that claimed "enhance element" are drawn to a genus of a nucleotide sequences i.e. enhancer element, controlling transcription of both human and rat Suppressed Gene-13 genes, that has to be identified in the future. The specification does not teach an enhancer element of Suppressed Gene-13 gene encoding SEQ ID NO:3 or 4.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. The specification fails to teach any structure of an enhancer element controlling expression of either a human and a rat transcripts encoding SEQ ID NO:2 or 4.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the

encompassed genus of “enhancer element” controlling expression of either a human and a rat transcripts encoding SEQ ID NO:2 or 4 given that the specification has only described SEQ ID NO:2 or 4 coding regions. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is separable from its enablement provision (see page 1115). This rejection affects all dependent claims.

Second, the specification as originally filed does not appear to have support for “operatively linking an enhance element” to an isolated nucleic acid encoding SEQ ID NO:2 or 4. The specification as originally filed at page 37 line 17 teaches an isolated nucleic acid encoding a rat Progression Suppressed Gene-13 protein is inserted into expression vector, and also teaches at bottom of page 6 making appropriate vector for a host cell, but the specification as originally filed does not seem to have support of operatively linking an enhance element to an isolated nucleic acid encoding SEQ ID NO:2 or 4. Applicant is kindly requested to point out the support because it is not apparent to the Office.

Claims 54-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making an art-known enhance element, does not reasonably provide enablement for an native enhancer element controlling the transcription of SEQ ID NO:2 or 4 coding region. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The base claims 54 and 70 as construed read on an isolated nucleic acid comprising SEQ ID NO:2 or 4 protein

coding region plus an native enhancer element controlling the transcription of said coding region. All dependent claims that have the rejected limitations are also rejected. See written description rejection above for interpretation of the claims. Darnell et al (Molecular Cell Biology, 1990, Scientific American Books, Inc., pages 296, and 344 only) teach that an enhancer is a DNA element that affects transcription and some enhancers have been found 40 kb or more either upstream or downstream from a gene of interest (note last two paragraphs of page 296, left column); this teaches that making an enhancer of a gene of interest (instance case, an enhancer controlling a human or a rat Suppressed Gene-13 gene transcript encoding SEQ ID NO:2 or 4) is not a trivial. L-24

Considering the limited teachings, no working example of an enhancer controlling a human or a rat Suppressed Gene-13 gene transcript encoding SEQ ID NO:2 or 4, unpredictability of art, it is concluded that undue experimentation is required to practice the full scope of the claimed invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne C Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER

MISOOK YU, Ph.D.
Examiner
Art Unit 1642